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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/293,835	04/19/1999	JAMES C. KENNEDY	067286/136/D	5426

7590

09/12/2002

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EXAMINER

SHARAREH, SHAHNAM J .

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 09/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/293,835

Applicant(s)

KENNEDY ET AL

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15, 18, 19, 24, 27-39, 41, 47 and 49-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15, 18, 19, 24, 27-39, 41, 47 and 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1617

DETAILED ACTION

9/15/02
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27-39, 41 47, 49-51 are pending.
Amendment filed on June 13, 2002 has been entered. Claims 1, 15, 18-19, 24,

Any rejection that is not addressed in this Office Action is considered withdrawn.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 15, 18-19, 24, ⁴¹27-39, 41-47, 49-51 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al US Patent 5,705,518 in view of Levy et al US Patent 5,283,255.

Applicant's arguments filed June 13, 2002 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, all elements of the pending claims have been taught in the cited references accordingly, the combined teachings of these references renders the instant claims prima facie obvious.

Applicant argues that Richter teaches the use of 5-ALA to target neovascular lesions and fungi do not have vessel and therefore, the teachings disclosed here would not be applicable to organisms without vascular systems.

In response, Examiner states that Applicant's arguments are scientifically and legally unfounded. Richter in col 5, line 53-55, teaches the use of his compositions in such types of conditions "characterized by neovascularization or hypervascularization." It is not clear what is meant by the term "neovascular lesions" interpreted by the Applicant. In fact, Examiner can not identify any lesions that is known in the art or classified as neovascular lesions. Thus, Applicant's interpretation of Richter does not appear to be accurate.

Assuming, arguendo, that neovascular lesion is a known medical condition, Reichter's statement does not mean that 5-ALA is to be used solely for such lesions. Neither, does he limit the use of 5-ALA to target neuovascular lesions. Rather, Reichter encourages the use of such compounds in any condition characterized by "revascularization" or "formation of new blood vessels." Such physiological occurrences are a common step within any inflammatory processes including skin infections. Accordingly, the ordinary skill in the art armed with Richter would have used topical 5-ALA for any infection characterized by neovascularization.

Levy is used to show that porphyrins are employed and thus effective not only in treatment of papiloma virus but also other skin infections such as athlete's foot which is caused by tinea pedis(see col 34, lines 60-67; col 35, lines 1-67, col 19, line 4).. Accordingly, using 5-ALA to treat skin conditions caused by tinea pedis would have been obvious because applying topical 5-aminolevulinic acid, as taught by Richter, to treat skin infections caused by tinea pedius or onychomycosis would have been expected.

Further, Applicant's arguments that 5-ALA may not even reach a potential target fungus or that there the cellular mechanism of phylogenetic continuum and a patient are not the same, have been fully considered but are not found persuasive as they are not commensurate with the scope of the pending claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Acting Supervisor, Russell Travers can be reached on 703-308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss
September 9, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200